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FREEDOM OF INFORMATION APPLICATIONS AS AN “EVERGREENING” TACTIC: SECRETARY, DEPARTMENT OF HEALTH AND AGEING v INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD (2010) 191 FCR 573; [2010] FCA 1442

*A recent decision of the Federal Court of Australia illustrates how patent-holding pharmaceutical companies are attempting to use Australia's Freedom of Information Act 1982 (Cth) to force Australian safety, quality and efficacy regulators to disclose whether generic competitors are attempting to enter the market. In *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 a single judge of the Federal Court overturned a decision of the Administrative Appeals Tribunal (AAT) that would have compelled the Australian Therapeutic Goods Administration (TGA) to reveal whether they were in possession of an application to register generic versions of two iNova products: imiquimod and phentermine. In its justification to the AAT for refusing to confirm or deny the existence of any application, the TGA argued that to reveal the existence of such a document would prejudice the proper administration of the National Health Act 1953 (Cth) as it could compromise the listing of a generic on the Pharmaceutical Benefits Scheme. The AAT failed to appreciate the extent to which this revelation to a competitor would have undercut 2004 amendments to the Therapeutic Goods Act 1989 (Cth) that provided penalties for evergreening tactics involving TGA notifications to drug patent-holders and 2006 amendments to the Patents Act 1990 (Cth) which protected the right of generic manufacturers to “springboard”. The decision of the Federal Court is one of the first to explore the use of freedom of information legislation by patent-holders as a potential “evergreening” technique to prolong royalties by marginalising generic competition. Because of the significant amounts of money involved in ensuring rapid market entry of low-cost generic products, the issue has considerable public health significance.*

INTRODUCTION

The decision of the Administrative Appeals Tribunal (AAT) in *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 and the Department's successful appeal in *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 illustrate the complex relationship between Australia's pharmaceutical regulator, the Therapeutic Goods Administration (TGA), and originator and generic sponsors. It is argued here that iNova Pharmaceuticals' use of the *Freedom of Information Act 1982* (Cth) (*Freedom of Information Act*) represents a new “pro-evergreening” tactic for patent-holders to track and take offensive actions to defend and extend their monopoly market share by discouraging the entry of generic products.

Although the AAT appeared unaware of the problem, similar “evergreening” strategies are being employed by other originator companies to delay or hinder the entry of generic medications, including

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copyright infringement proceedings to protect Product Information forms,¹ deceptive and misleading advertising to health professionals,² and the filing of incremental method and use “evergreening” patents.³ Early identification of a competitor’s intention to list a generic product may also provide originator companies with an opportunity to use a variety of tactics to push out competition prior to the TGA notification which activates the “anti-evergreening” amendments in the *Therapeutic Goods Act 1989* (*Therapeutic Goods Act*).⁴ Such actions by a patent-holder would, in effect, amount to a unilateral interpretation of the so-called “patent status-safety linkage” provision in Art 17.10.4 of the *Australia–United States Free Trade Agreement* (AUSFTA).⁵ Given the recognised commercial value of knowing when a competitor, and which one, is preparing to introduce a generic product, it is useful to explore what protection, if any, regulators are able to provide applicants.⁶

BACKGROUND TO THE ATT APPEAL

Several iNova’s products contain as their active ingredients either imiquimod or phentermine. These products are marketed under the brand names Aldara and Duromine respectively. Phentermine is also sold by iNova in Australia under the name Metermine and, while all three drugs are listed on the Australian Register of Therapeutic Goods (ARTG), Duromine is not listed on the Pharmaceutical Benefits Scheme (PBS). Phentamine is the active ingredient in a number of appetite suppressant drugs and is now off-patent; however, iNova’s patent over imiquimod, which is used in the treatment of external genital and perianal warts and solar keratosis on the face and scalp, does not expire until 2013.⁷ Approximately 23,000 PBS prescriptions were dispensed for imiquimod in the 2009 calendar year, with the Commonwealth paying a subsidy of \$3.3 million.⁸ The total expenditure⁹ for the PBS in the financial year to June 2010 was \$8,342.03 million.¹⁰

On 22 October 2009, iNova lodged a freedom of information request with the TGA, seeking

¹ Anon, “PI Copyright Case in Court”, *PharmaInFocus* (10 March 2011), <http://www.pharmainfocus.com.au> viewed 10 March 2011.

² Faunce TA, Vines T and Gibbons H, “New Forms of Evergreening in Australia: Misleading Advertising, Enantiomers and Data Exclusivity: *Apotex v Servier* and *Alphapharm v Lundbeck*” in “Medical Law Reporter” (2008) 16 JLM 220.

³ Faunce TA and Lexchin J, “‘Linkage’ Pharmaceutical Evergreening in Canada and Australia” (2007) 4(1) *Australian and New Zealand Journal of Health Policy* 8.

⁴ Section 26C of the *Therapeutic Goods Act 1989* (Cth) provides for pecuniary penalties of up to \$10 million against a litigant who commences a patent infringement suit not in “good faith”. Medicines Australia and the United States Pharmaceutical Industry have continually called for the repeal of s 26C: *Medicines Australia Submission to the Expert Panel Review of the National Innovation System* (2008) pp 3, 7, <http://www.medicinesaustralia.com.au/files/2010/02/MA-submission-Expert-Panel-National-Innovation-System-Review-April-2008.pdf> viewed 30 April 2011; *Medicines Australia Submission to Australian Council of Intellectual Property Review of Post-Grant Patent Enforcement Strategies* (October 2009) p 3, <http://www.medicinesaustralia.com.au/files/2010/08/MA-Submission-to-ACIP-on-Post-Grant-Patent-Enforcement-Strategies.pdf> viewed 30 April 2011.

⁵ *Australia–United States Free Trade Agreement* [2005] ATS 1 opened for signature 18 May 2004, Washington, entered into force in Australia 1 January 2005.

⁶ Indeed, two companies, IMS and Dun & Bradstreet, were identified as private commercial intelligence gathering agencies: *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [42].

⁷ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [5].

⁸ *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 at [32].

⁹ Department of Health and Ageing, *Expenditure and Prescriptions Twelve Months to 30 June 2009* (December 2009), <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-stats-pbexp-jun09> viewed 8 March 2011.

¹⁰ Pharmaceutical Benefits Pricing Authority, *Annual Report* (2010) p 9.

a copy of any correspondence received by the Therapeutic Goods Administration and/or accepting into evaluation any Category 1 and/or Category 3 applications to register a therapeutic product containing the active ingredient phentermine made by sponsors other than iNova Pharmaceuticals in 2008-2009.¹¹

On the same date, iNova also sought the same information in relation to any therapeutics containing imiquimod. During the hearing in the AAT it emerged that iNova had been making similar requests for information on products containing imiquimod since April 2009. Prior requests for information were refused on the grounds – set out in s 24 of the *Freedom of Information Act* – that the relevant documents could not be found or did not exist.¹²

On 17 November 2009, however, the Department refused to release the requested information without confirming or denying the existence of any such documents. Following an internal review, preliminary appeal to the AAT and remittal back to the Department, a new decision to refuse access to the document and refusal to confirm or deny their existence was made by Dr Ruth Lopert, the Principal Medical Adviser in the TGA and delegate to the Secretary for the relevant freedom of information decisions.¹³ Dr Lopert played a central role in Australia's negotiations of the "patent status-safety linkage" provisions of the AUSFTA and, as a Harkness Fellow, has significant expertise in the "evergreening" phenomenon in the United States and Canada.

A key dispute before the AAT was the question of whether the TGA could rely on ss 26 and 25 of the *Freedom of Information Act* to refuse to disclose the existence (or non-existence) of any application for the listing of a generic product on the ARTG generally. An additional, and perhaps more interesting, submission put by the TGA to the AAT and Federal Court of Australia was that the TGA had a responsibility to ensure the proper administration of the PBS. Therefore, the TGA was entitled to refuse to confirm or deny the existence of a document relating to a possible application for listing a generic product on the ARTG on the grounds set out in s 37(1)(a) of the *Freedom of Information Act*.

Before discussing the specific arguments put forward by both parties, it is necessary to provide a brief overview of the *Freedom of Information Act* as it applied at the time, with a focus on the rights and obligations of iNova and the TGA.

AUSTRALIAN FREEDOM OF INFORMATION LAWS

Freedom of information laws in Australia are the responsibility of the States and Territories as well as the Commonwealth.¹⁴ The *Freedom of Information Act 1982* (Cth) applies to all Commonwealth Departments, prescribed agencies and to federal courts and administrative tribunals when acting in an administrative capacity.¹⁵ In 2010 the *Freedom of Information Amendment (Reform) Bill* (*Freedom of Information Reform Bill*) was passed by Parliament,¹⁶ with the majority of its provisions coming into force from October 2010.¹⁷ Both the original AAT appeal and Federal Court appeals were conducted under the provisions of the pre-reform *Freedom of Information Act*. However, except where it is necessary to draw attention to differences in the provisions, this analysis uses the section numbering of the post-reform *Freedom of Information Act*.

¹¹ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [7].

¹² *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [41].

¹³ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [8]-[10].

¹⁴ See eg *Freedom of Information Act 1989* (ACT); *Government Information (Public Access) Act 2009* (NSW); *Right to Information Act 2009* (Qld); *Freedom of Information Act 1982* (Vic).

¹⁵ *Freedom of Information Act 1982* (Cth), ss 4, 5, 6; however, under s 7 there are standing exceptions from the Act for security and national defence organisations. See also Sch 2 of the *Freedom of Information Act 1982* (Cth). For simplicity, information held by these bodies will hereafter be referred to as "government information".

¹⁶ Enacted as the *Freedom of Information Amendment (Reform) Act 2010* (Cth).

¹⁷ Provisions relating to the mandatory publication of information released under freedom of information requests entered into force on 1 May 2011. This scheme is not relevant to the cases discussed.

Section 11 of the *Freedom of Information Act* grants “every person” a “legally enforceable right” to access government information. As a rule of statutory construction, “person” includes corporate bodies such as iNova.¹⁸ Section 11A(3) creates a mandatory obligation on the Minister or agency to release non-exempted information, subject to the payment of any necessary fees. In most cases a decision whether to release the documents must be made within 30 days of receipt of the request by an agency.¹⁹ A Minister or agency may only refuse to release information if it is an exempt document for the purposes of ss 12, 13, 14 or Pt IV of the *Freedom of Information Act*.

Under Pt IV of the *reformed Act*, exemptions are only available for:

- documents affecting national security, defence or international relations (s 33);
- Cabinet documents (s 34);
- documents affecting enforcement of law and protection of public health (s 37);²⁰
- documents to which secrecy provisions of enactments apply (s 38);
- documents subject to legal professional privilege (s 42);
- documents containing material obtained in confidence (s 45);
- documents the disclosure of which would be contempt of Parliament or contempt of court (s 46);
- documents disclosing trade secrets or commercially valuable information (s 47); and
- the electoral rolls and related documents (s 47A).

An objective of the *Freedom of Information Reform Bill* was to limit the range of exempt documents.²¹ To that end, the *Freedom of Information Act* now provides that many documents, which had previously been exempt, are now “conditionally-exempt”. Conditionally-exempt documents *must* be released if the release of the document would not be contrary to the public interest.²² At the time of the *iNova* decision and appeal, however, the pre-reform Act applied and the TGA argued that, if the documents existed, they would be exempt documents under Pt IV.²³

Section 26 of the Act requires agencies to provide a notice of reasons when refusing access to a document. The notice must:

- (a) state the findings on any material questions of fact, referring to the material on which those findings were based, and state the reasons for the decision;
- (b) where the decision relates to a document of an agency, state the name and designation of the person giving the decision; and
- (c) give to the applicant appropriate information concerning:
 - (i) his or her rights with respect to review of the decision;
 - (ii) his or her rights to make a complaint to the Ombudsman in relation to the decision; and
 - (iii) the procedure for the exercise of the rights referred to in subparagraphs (i) and (ii); including (where applicable) particulars of the manner in which an application for review ... may be made.

The general right to reasons provided for in s 26(1) is conditioned by s 26(2):

A notice under this section is not required to contain any matter that is of such a nature that its inclusion in a document of an agency would cause that document to be an exempt document.

The TGA argued that, in the case of phentermine, to disclose the existence of the requested document in a notice to iNova would result in *that notice* becoming an exempt document. As such, it

¹⁸ *Acts Interpretation Act 1901* (Cth), s 22(1)(a).

¹⁹ *Freedom of Information Act 1982* (Cth), s 15(5)(b).

²⁰ Gaps in the sequence of sections reflect amendments to the *Freedom of Information Act 1982* (Cth).

²¹ See eg Australian Parliament, *Freedom of Information Amendment (Reform) Bill 2010*, Explanatory Memorandum, http://www.austlii.edu.au/au/legis/cth/bill_em/foiab2010381/memo_0.html viewed 9 March 2011; Faulkner J, Senator, *Open Government and Freedom of Information: Letter to Departmental Secretaries and Agency Heads* (30 April 2009), http://www.dpmc.gov.au/consultation/foi_reform/docs/letter_to_secretaries_FOI.pdf viewed 9 March 2011.

²² See *Freedom of Information Act 1982* (Cth), ss 47B–47J.

²³ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [11], [14].

was open for the TGA to refuse to confirm or deny the existence of the document sought by iNova in their notice. Furthermore, an Agency is under no obligation to provide information “as to the existence or non-existence” of a document,

where information as to the existence or non-existence of that document, if included in a document of an agency, would cause the last-mentioned document to be an exempt document by virtue of section 33 [documents affecting national security, defence or international relations] or 33A [documents affecting relations with States] or subsection 37(1) [documents the disclosure of which could reasonably be expected to ... prejudice the proper administration of the law...].²⁴

In the case of *imiquimod*, Dr Lopert of the TGA, relying on s 25(1) of the *Freedom of Information Act*, argued that, if an application existed, it would be exempt under s 37(1) because the information, if disclosed, “could reasonably be expected to prejudice the proper administration of the law in a particular instance”.²⁵ More specifically, Dr Lopert argued that the disclosure of the information “would be used to obtain a financial advantage against the Commonwealth in the sale of certain medicines under the PBS thereby prejudicing the administration of the *National Health Act 1953*”.²⁶ Such an advantage to iNova would arise if it took steps to prevent a generic version of its Aldara products from being placed on the PBS, where that listing would trigger a mandatory reduction in the subsidy paid to iNova for its products.

Prior to 1 February 2011, s 99ACB of the *National Health Act 1953* (Cth) imposed a 12.5% reduction in the subsidised price paid for the originator’s product once a bio-equivalent generic is listed on the PBS. From 1 February 2011 this reduction increased to 16%.²⁷ Delay in the introduction of a generic would, therefore, confer a valuable commercial benefit to iNova. Not only would their \$3 million a year market be subject to less competition but their own product would not be subject to the 12.5% (now 16%) price cut, which Dr Lopert estimated would save the community (ie cost iNova) approximately \$400,000 per year.²⁸

Dr Lopert did not rely on s 37(1) for refusing to acknowledge the existence of a document related to phentermine, instead relying on the exemptions contained in ss 43(1)(b) and 45(1) of the *Freedom of Information Act*.²⁹ This is understandable as iNova’s other product, Duromine, was off-patent and was not listed on the PBS. As such, the opportunities for delaying the entry of a generic were fewer and would not, in any event, prejudice any price reduction under s 99ACB.

PROTECTING AGAINST EVERGREENING: THE TGA’S ARGUMENTS TO THE AAT

At the centre of the TGA’s arguments were two concerns. First, due to the small generic sector in Australia, any confirmation of the existence of an application to list a generic product on the ARTG is likely to lead to the identification of the applicant.³⁰ iNova’s counsel disputed the ease with which iNova could have identified the applicant, highlighting that although there are only five members of the Generic Medicines Association, not all generic manufacturers belong to this organisation and, in

²⁴ *Freedom of Information Act 1982* (Cth), s 25(1). This provision was unchanged by the *Freedom of Information Reform Bill*. See *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [26].

²⁵ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [15] referencing s 37(1) of the *Freedom of Information Act 1982* (Cth).

²⁶ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [15].

²⁷ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [39].

²⁸ *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 at [32].

²⁹ Documents relating to business affairs and documents containing material obtained in confidence, respectively.

³⁰ *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 at [46].

any event, many originator companies also sell generic medicines.³¹ While this may be true, it does not mitigate the second concern of the TGA: that, once identified, iNova could take adverse steps against the applicant to delay the entry of the generic product and thus prejudice the administration of the *National Health Act*.

Defending the refusal to confirm or deny the existence of the documents, Dr Lopert referred to the case of *Wyeth v Department of Health and Ageing* (2009) 255 ALR 352; [2009] FCA 313 where the company (Wyeth) had lodged a freedom of information application with the TGA seeking information whether the TGA had received any applications for products containing the active ingredient venlafaxine, over which it owned a patent (at [2], [3]). When the TGA confirmed the existence of such applications (but not the identity of the companies), Wyeth filed for preliminary discovery as a preliminary step to seeking injunctive relief against the applicants (at [4]). Although that motion was denied, it undermines iNova's claim "not to be aware of how iNova could delay an application for listing by the TGA once accepted".³²

Dr Lopert also referred to other strategies that could be used to delay the entry of a generic product onto the market, including:

taking injunctive action against regulators, changing the originator product to make the demonstration of bio-equivalence more difficult (for example, developing a long acting preparation to avoid bioequivalence), entering into covert arrangements with generics companies and offering inducements to delay market entry, and registering and marketing one or more pseudo-generic brands.³³

The AAT rejected Dr Lopert's concerns as "entirely speculative",³⁴ with counsel for the appellant suggesting Dr Lopert's arguments "appear[ed] to be an expression of her personal opinions about competition in the pharmaceutical industry... [and] ... disapproval of reliance on the law of patents by originator sponsors".³⁵ The AAT's curt dismissal of such expert testimony about patented pharmaceutical industry "evergreening" tactics displays a misunderstanding and/or ignorance about the "evergreening" process in the United States, Canada and Australia.

In 2006 the *Patents Act 1990* (Cth) was amended to include the new s 119A. This clarified and extended the "springboarding" exemption that permitted generic manufacturers to submit applications to the TGA prior to their competitor's patent expiry in order to be ready as soon as possible after that date to launch their cheaper but bioequivalent products. The new exemption applied to patents claiming a pharmaceutical substance, method, use, or product and permitted springboarding at any time during the life of a pharmaceutical patent, whether its term had been extended or not.

Although not raised by Dr Lopert, a litigation advantage may accrue to an originator company which is able to identify a competitor early in the regulatory approval process. Anti-evergreening provisions exist in the *Therapeutic Goods Act* to discourage one company (usually a patent-holding company) from preventing, delaying or discouraging the market entry of a generic prescription medication.³⁶ These amendments were a concession by the Howard Government to ensure the passage of the legislation implementing AUSFTA and have been bitterly opposed by Medicines Australia and United States Trade Representatives, despite being technically non-discriminatory under the World

³¹ *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 at [46].

³² *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 at [48].

³³ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [27].

³⁴ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [58].

³⁵ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [59].

³⁶ *Therapeutic Goods Act 1989* (Cth), ss 26B, 26C and 26D.

Trade Organisation (WTO) Trade-Related Intellectual Property (TRIPS) agreement as regulating a problem (“evergreening”) that arises solely in the pharmaceutical industry.³⁷

Importantly, a generic manufacturer seeking the registration of their product is only required to provide a Certificate under s 26B of the *Therapeutic Goods Act* “once the evaluation of the safety, efficacy and quality of the goods has been completed under section 25 of the *Therapeutic Goods Act* and the decision is to register the goods”.³⁸ As an originator company is only liable to a potential pecuniary cost order of \$10 million if the other party has filed a s 26B certificate with the TGA, this period of assessment provides an opportunity to commence patent infringement litigation (which is vexatious, frivolous or otherwise not done in good faith) without fear of activating the anti-evergreening penalty provisions set out in ss 26C and 26D of the *Therapeutic Goods Act*.

The gist of the Department’s argument was as follows: given the role of the Minister for Health and Ageing (acting through her delegates at the Department of Health and Ageing and the TGA) in administering the *National Health Act*, any release of information which could possibly negatively affect the PBS listing process would undermine the operation of the law. Consequently, it could rely on the exclusions under the *Freedom of Information Act* to refuse to confirm or deny the existence of the documents.

THE RELATIONSHIP BETWEEN THE TGA AND THE PBS

Under the *Therapeutic Goods Act*, the TGA is responsible for evaluating the quality (batch standardisation), safety (toxicology) and efficacy (clinical effect) of therapeutic products.³⁹ Before a new medicine (or a new use for an existing medicine) can be manufactured, sold or advertised for sale in Australia, the medicine’s “sponsor” must lodge an application with the TGA for inclusion of the good on the ARTG.⁴⁰ Once the TGA has listed the medicine on the ARTG, a sponsor can then apply to have the product listed on the PBS. Over 75% of purchased prescription medicines in Australia are listed on the PBS,⁴¹ making PBS listing a commercial imperative.

The Pharmaceutical Benefits Advisory Committee (PBAC) determines a submission for inclusion on the PBS, with final pricing arrangements negotiated between the sponsor and the Pharmaceutical Benefits Pricing Authority. An application for inclusion on the PBS can run in parallel with an application for listing on the ARTG but they are usually sequential. The price of a pharmaceutical newly added to the PBS is referenced against the lowest priced, interchangeable drug within the relevant therapeutic group. In theory, once a pharmaceutical comes off-patent, the entry of a new generic version will drive down the cost of the listed medicine and, consequently, its cost to the Australian community. Recent reforms to the PBS⁴² and the Memorandum of Understanding⁴³ between the Australian Government and the patented pharmaceutical manufacturers lobby group, Medicines Australia, to lower the price of generic medicines, however, have weakened the ability of price referencing to reduce the price of off-patent pharmaceuticals.⁴⁴

³⁷ See further Faunce and Lexchin, n 3.

³⁸ *Certification in Relation to Patents Required in Relation to Registration or Listing under Sections 25, 26 and 26A of the Therapeutic Goods Act 1989 (TGA)*, <http://www.tga.gov.au/international/usftacert26b.pdf> viewed 30 April 2011.

³⁹ *Therapeutic Goods Act 1989* (Cth), s 4.

⁴⁰ *Therapeutic Goods Act 1989* (Cth), ss 19B, 19D-22 create a range of civil and criminal offences for importing, exporting, manufacturing or supplying a therapeutic good for use in humans that is not listed on the ARTG.

⁴¹ Clarke PM and Fitzgerald EM, *Expiry of Patent Protection on Statins: Effects on Pharmaceutical Expenditure in Australia* (2010) 192(11) MJA 633, http://www.mja.com.au/public/issues/192_11_070610/cla11057_fm.html viewed 30 April 2011.

⁴² Faunce TA, Bai J and Nguyen D, “Impact of the Australia–US Free Trade Agreement on Australian Medicines Regulation and Prices” (2010) 7(1) *Journal of Generic Medicines* 18; Faunce TA and Lofgren H, “Drug Price Reforms: The New F1-F2 Bifurcation” (2007) 30(6) *Australian Prescriber* 138.

⁴³ *Memorandum of Understanding between the Australian Government and Medicines Australia* (2010), [http://www.health.gov.au/internet/main/publishing.nsf/Content/C6EC4D1258BBFFB6CA257721000520A2/\\$File/MOU%20MA.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/C6EC4D1258BBFFB6CA257721000520A2/$File/MOU%20MA.pdf) viewed 30 April 2011.

⁴⁴ Simoens SRA, *Expiry of Patent Protection on Statins: Effects on Pharmaceutical Expenditure in Australia* (2011) 194(1)

Importantly, however, the functions and responsibilities of the TGA are set out in the *Therapeutic Goods Act*, while the PBS is administered by the Department of Health and Ageing under the *National Health Act*.⁴⁵

FEDERAL COURT REJECTION OF THE AAT'S FINDINGS AND REASONING

Ultimately, the AAT rejected the arguments of the Department and ordered the Department to provide iNova with a response to their freedom of information request – effectively revealing whether or not an application to register a generic product existed. Overturning the Department's decision in relation to phentamine, the AAT held that, were the Department's submission on the construction of s 26(2) of the *Freedom of Information Act* correct, it would render the more limited exemption afforded by s 25(1) "otiose".⁴⁶ The effect of this ruling, had it not been overturned, would have limited the ability of the government to issue a "refuse to confirm or deny" response except where the putative document satisfied the more restricted exemption provided by s 25(1).

In the matter of imiquimod, the AAT examined whether the Department had formed a reasonable belief that the release of any information confirming or denying the existence of an application would prejudice the proper administration of the law. While the AAT did not reject the Department's submission that the TGA had a role in ensuring the proper administration of the PBS, it held that the Department had not

[established] its contention that the delay consequent upon action taken by iNova would flow through to the listing of the medicine on the PBS, and would have an adverse effect on the Department's ability to obtain value for Australian taxpayers' money.⁴⁷

The AAT held that reliance on s 37(1)(a) of the *Freedom of Information Act* required the decision-maker to reach a sound judgment that the release of the information "could reasonably be expected to" prejudice the proper administration of the law.⁴⁸ To satisfy this test, the AAT argued that the decision-maker needed to establish the following five criteria:

- (1) that disclosure of the existence of an application for ARTG listing of a bioequivalent generic product would lead to iNova being able to identify the sponsor of the generic product;
- (2) that iNova would take consequent action on discovering the identity of the sponsor of the generic product;
- (3) that such action by iNova would delay the ARTG listing of the generic product;
- (4) that a delay in ARTG listing would result in a delay in PBS listing; and
- (5) that a delay in PBS listing would delay a reduction in the subsidy provided by the government for the originator product.⁴⁹

Though the AAT accepted that a delay in ARTG listing would result in a delay in PBS listing (point (4)) and that any delay in PBS listing "could result" in a delay in reducing the subsidy paid to

MJA 52 (Letters), http://www.mja.com.au/public/issues/194_01_030111/letters_030111_fm-7.html viewed 30 April 2011; Clarke and Fitzgerald, n 41; Faunce TA, "Reference Pricing for Pharmaceuticals: Is the Australia–United States Free Trade Agreement Affecting Australia's Pharmaceutical Benefits Scheme?" (2007) 187(4) MJA 240 (eMJA rapid online publication 13 June 2007).

⁴⁵ Importantly, the TGA is a division of the Department of Health and Ageing and is not a separate portfolio agency.

⁴⁶ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [34]. The AAT relied on the principles of statutory interpretation set out in *Anthony Hordern & Sons Ltd v Amalgamated Clothing and Allied Trades Union of Australia* (1932) 47 CLR 1 at 7 (Gavan Duffy CJ and Dixon J); *R v Wallis* (1949) 78 CLR 529 at 550 (Dixon J).

⁴⁷ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 (at [65]).

⁴⁸ *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 at [36] (emphasis added).

⁴⁹ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [65]. The AAT also indicated that success on point (5) was unlikely to assist the Department as any price reduction triggered by the listing of a generic product was "effected by operation of law rather than as a consequence of how the law is administered in a particular instance" (at [70]). Consequently, the TGA could not argue that the release of the document would affect the proper administration of the law.

an originator company (point (5)),⁵⁰ it found that the Department had not established the other criteria.⁵¹ Crucially, it held that the Department had not demonstrated any capacity for iNova to frustrate the registration of a product on the ARTG once an application had been submitted. As such, reliance on s 37(1)(a) was unavailable to the Department and, therefore, it could not refuse to “confirm or deny” the existence of an application under s 25(1) of the Act.

Ultimately, the practical effect of the AAT decision (had it not been successfully appealed) would have been limited to compelling the Department to confirm the existence of an application to register a generic product. The Department may still have been able to rely on other provisions to exempt the actual application from release. Indeed, given that the pre-reform *Freedom of Information Act* included provisions preventing the release of commercial in-confidence information, this would have been an almost certainty. Nonetheless, if, as the Department had argued, the prejudice to the PBS would arise from the mere disclosure of the existence of the document, there could have been significant consequences for the generic company identified as the applicant.

On appeal in *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 (at [59]), the Federal Court rejected the reasoning of the AAT in relation to the ability of the Department to rely on s 26 of the *Freedom of Information Act*, as well as s 25, to refuse to confirm or deny the existence of a document. Rather, the court found that ss 25 and 26 “are directed at different questions”. In distinguishing the “work” required of both sections, the court held (at [60]):

Section 25 of the FOI Act has work to do, notwithstanding that other provisions in the FOI Act authorise a similar mechanism for protecting certain kinds of information. Section 25 authorises a response that neither confirms nor denies the existence of documents, absent any search for documents of the kind requested. A similar response under s 26(2) is authorised, after a search has been undertaken. That response, however, is permitted only where the inclusion of information about documents would make the notice required under s 26(1) itself an exempt document.

While the court’s decision, on its face, supported the original decision of the TGA, in practical terms it weakened the protection afforded to an applicant under s 26(1) of the *Freedom of Information Act*. As the court itself noted (at [61]):

An informed person would know that a response neither confirming nor denying the existence of a document [pursuant to s 26 of the *Freedom of Information Act*] necessarily implied that there were such documents because, on the view contended for, the agency would be bound to state that there were no documents.

Indeed, the court went so far as to suggest a possible strategy for a patent holder to monitor the TGA for signs of new listing activity (at [62]):

[A] person making a request under the FOI Act ... could make periodic requests for the same information in order to see whether the form of the response changed over time [ie from “no document exists” to a refusal to “confirm or deny” the existence of a document]. According to the frequency with which requests were made, that person could determine when a document [ie application to register a competitor product] first existed.

Whether it is desirable for courts to offer in their judgments new, “judicially approved” models for circumventing the spirit of a law is a question best considered by the courts themselves. In a different IP context, the full Bench of the Federal Court has recently provided what many argue is a “how-to” guide for content owners to effectively build a case against an internet service provider for copyright infringement authorisation.⁵² While it is clear and proper that industry and other parties will model future practice on the determinations of a court, it may be a step too far for the courts themselves to provide a draft standard-operating procedure in their obiter.

⁵⁰ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [70].

⁵¹ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [66]-[69].

⁵² *Roadshow Films Pty Ltd v iiNet Ltd* (2011) 275 ALR 1; [2011] FCAFC 23; anon, “Federal Court Rules Against Hollywood” (24 February 2011), *Lawyers Weekly* (online), http://www.lawyersweekly.com.au/blogs/top_stories/archive/2011/02/24/federal-court-rules-against-hollywood.aspx viewed 30 April 2011; AFACT, “iiNet Decision: Judges Pave the Way for ISPs to be Held

Having found in favour of the Department's use of s 26, it was not strictly necessary for the court to further consider the AAT's finding that the Department could not rely on s 37(1)(a) of the *Freedom of Information Act* (at [66]). However, the court held (at [67]-[68]) that the five criteria set out by the AAT⁵³ were misconstrued as they placed too heavy an emphasis on iNova's state of mind and capacity to identify a putative applicant. Section 37(1)(a) of the *Freedom of Information Act* sets out an objective test, with the decision-maker only needing to form a reasonable belief that disclosure "would, or could reasonably be expected to, prejudice the enforcement or proper administration of the law". The AAT fell into error by holding that the Department had to form a belief that iNova per se had the capacity to prejudice the proper administration of the law (at [67]). Rather, so long as it "could reasonably be expected" that *anyone* could prejudice the effective administration of the law, then a decision-maker could rely on s 37(1)(a) (at [67]). It is not clear who, other than the patentee, would seek to prejudice the administration of the PBS and the court did not provide any examples. Thus, while the court upheld the original decision of the TGA, it is a partial victory at best, with more guidance provided to industry than to bureaucrats in how to "work" the *Freedom of Information Act*.

CONCLUSION

The TGA's submissions to both the AAT and the Federal Court represent a bold claim to be a joint administrator of the PBS, and presume a logical or inevitable connection between an application for listing a therapeutic good on the ARTG and a submission to the PBAC for inclusion of that product on the PBS. Recent decisions by the Federal Cabinet to defer consideration of PBAC recommendations to temporarily protect the budget bottom line do not undermine this line of logic. However, while the TGA remains part of the Department of Health and Ageing, the decision of the Federal Court in *Secretary, Department of Health and Ageing v iNova* appears on its face to support the TGA's reliance on ss 25(1) and 26(2) of the *Freedom of Information Act* to protect the identity of generic manufacturers seeking to register a product containing a patented ingredient.

In practice, however, the Federal Court's decision highlights the need for the Australian Federal Government to create a multidisciplinary oversight body of this area similar to the Office of Patented Medicines and Liaison operating under Health Canada. As the Federal Court explained, the present under-regulated system permits a patented pharmaceutical freedom of information applicant to submit multiple freedom of information requests over a period of time, "fishing" for a change in the form of a rejection letter as a signal that an application by a potential generic competitor had been received. The problem is a significant one and will not simply go away. Early commencement of litigation in the registration process may also confer an additional advantage on an originator company which could run litigation as a delaying tactic without fear of being subject to a \$10 million cost order under s 26D of the *Therapeutic Goods Act*.

Nonetheless, by affirming the responsibility of the TGA to properly administer the PBS, the value of freedom of information requests by originator companies may be seen as a less effective tool to monitor and pre-empt the entry of competitors into the market. Australia needs an "evergreening" oversight body. Protracted desuetude is not a practical regulatory option in this instance.

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Accountable for Online Infringements", *Media Release* (February 2011), <http://www.afact.org.au/pressreleases/2011/25-2-2011.html> viewed 30 April 2011.

⁵³ *iNova Pharmaceuticals (Australia) Pty Ltd v Secretary, Department of Health and Ageing* (2010) 116 ALD 448; [2010] AATA 542 at [65].